REMARKS

Claims 33-40 and 42-53 were pending in the application and were rejected. Claims 42-46 are herein cancelled. Claims 33 and 36-39 are amended. Claim 54 is new. None of the amended or new claims introduce new subject matter. Claims 36-39 are amended to correct antecedent basis. New claim 54 is supported at paragraph [0022] of the published application and former claim 40. The amendments make corrections requested and expected by the Examiner or delete limitations. No new claim limitations are introduced by these amended and new claims, so no new search of the claims is necessitated.

On June 3, 2008 Applicant's representative conducted a phone interview with Examiners Xie and Kemmerer. The substance of the interview was correctly summarized by the Examiner in the Office Communication of June 4, 2008.

35 USC § 112, First Paragraph

Current claims 40 and 47-52 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement and failing to provide enabling description to use the method as claimed.

As amended, claims 40 and 47-52 are directed to treatment with human apo-lactoferrin, and/or human lactoferricin. The Examiner conceded in the Office Action mailed June 1, 2007 at p. 6 bottom that the subject matter of such claims is enabled.

For these reasons, Applicant asserts that the claims fulfill the written description requirement and are supported by enabling description. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

35 USC § 112, Second Paragraph

Claims 33 and 36-39 were rejected under 35 USC § 112, second paragraph, as being indefinite.

The claims have been amended to correct all the antecedent basis and grammar issues. It is believed all the claims are now definite.

35 USC § 102

Claims 33-40, 42-44 and 47-52 were rejected under 35 USC § 102 as being anticipated by Miller et al (U.S. Patent No. 6,426,362). Applicant traverses the rejection.

Claims 33-39 are directed to a method for treatment of a vascular disease or states of tissue hypoperfusion wherein the disease or tissue state leads to hypoxia or ischemia, the method comprising administering a therapeutically effective amount of human apo-lactoferrin. In contrast, Miller et al. teach a method of treating the disruption of energy metabolism or ameliorating injury secondary to stress, which requires administering a composition of tocopherol along with a synergistic agent, in which the synergistic agent may be a human apo-lactoferrin.

Miller et al. teaches that if the synergistic agent is administered individually, it is ineffective for the intended therapeutic purpose (Col. 47, lines 60-63). Therefore, Miller's teaching is incompatible with Applicant's claimed method. For this reason, Miller et al. does not anticipate the claims.

Furthermore, Applicant's claimed invention includes a limitation of administering a therapeutically effective amount of human apo-lactoferrin. The therapeutically effective amount is defined in the specification as relating to an amount that will "lead to the desired therapeutic effect, i.e. an amount that will enhance the VEGF mediated angiogenesis." (Specification, page 7, lines 25-28). Miller et al. do not describe a therapeutically effective amount of apo-lactoferrin that will enhance VEGF mediated angiogenesis. This is yet another reason that Miller et al. fails to disclose each and every element of claims 33-39. For this reason, the claims are novel over Miller et al.

Furthermore, since Miller et al. fail to disclose any of the additional limitations disclosed in claim 35, this constitutes yet a third reason why claim 35 is novel over Miller et al.

Claims 40 and 47-54 are directed to a method for treatment of a vascular disease or states of tissue hypoperfusion wherein the method includes determining a therapeutically effective amount of a substance that is active in stimulating VEGF-mediated angiogenesis and the administered treatment is human apo-lactoferrin or human lactoferricin. Human lactoferricin is not disclosed by Miller et al. A therapeutically effective amount of human apo-lactoferrin is not

disclosed by Miller et al. Therefore, claims 40-54 are novel over U.S. Patent No. 6,426,362 to Miller et al.

For all the reasons discussed above, Applicants respectfully request that the rejections under 35 U.S.C. 102 be reconsidered and withdrawn.

35 USC § 103

Claims 33-40 and 47-53 were rejected under 35 USC § 103(a) as being unpatentable over Hiroki et al. (JP 09-194388) in view of Clement (Acta Chir. Belg., 2000, 100:190-193). Applicant traverses the rejection.

Claims 33-40 and 47-53 are directed to a method for treatment of a vascular disease or states of tissue hypoperfusion comprising administering a therapeutically effective amount of human apo-lactoferrin or human lactoferricin. Apo-lactoferrin is an iron-depleted form of lactoferrin. The Examiner states that Hiroki et al. at paragraph [0012] teach that the lactoferrin in their treatment can be isolated from human milk and is iron-unsaturated (apo-lactoferrin). Hiroki et al. is a computer-generated translation from the Japanese language and paragraph [0012] is grammatically unreadable in the English language to Applicant's representative. The paragraph, in its entirety reads as follows:

[0012]

[Embodiments of the Invention] The lactoferrin used as an active principle of the vascularization disease treatment agent of this invention The appointment lactoferrin which removed iron from Lf(s) separated from commercial Lf, ****, and human milk by the conventional method, and these Lf(s) by the conventional method, It is the metal saturation the chelate of the metals, such as iron, copper, zinc, and manganese, was completely carried out [saturation] to appointment lactoferrin in part by the conventional method, or the general term of metal part saturation lactoferrin, and any one sort or two sorts or more of such mixture can be used.

Since the above paragraph reads as gibberish, Applicant challenges the Examiner's statement that Hiroki et al. teach that human apo-lactoferrin is used in their method of treatment. In view of the fact that such a showing is lacking in the translation provided by the Examiner, it is respectfully asserted that the Examiner has failed to show that the prior art teaches every aspect of claims 33-39, so there has been no *prima facie* showing of obviousness.

Claims 40 and 47-54 are directed to a method for treatment of a vascular disease or states of tissue hypoperfusion wherein the administered treatment is for human apo-lactoferrin or

human lactoferricin. None of these agents are disclosed by Hiroki et al. or by Clement. For this reason, it is respectfully asserted that the Examiner has failed to show that the prior art teaches every aspect of claims 40 and 47-54. Thus, there has been no *prima facie* showing of obviousness.

For all the reasons discussed above, Applicants respectfully request that the rejections under 35 U.S.C. 103 be reconsidered and withdrawn.

In view of the foregoing, Applicant submits that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should the Examiner believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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